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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,528	10/30/2001	Bill Minshall	MINSH-001A	9635
7663	7590	05/25/2004	EXAMINER	
STETINA BRUNDA GARRED & BRUCKER 75 ENTERPRISE, SUITE 250 ALISO VIEJO, CA 92656			YAEN, CHRISTOPHER H	
		ART UNIT	PAPER NUMBER	
		1642		

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/016,528	MINSHALL ET AL.
	Examiner	Art Unit
	Christopher H Yaen	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,5-7,10,11 and 13-39 is/are pending in the application.
- 4a) Of the above claim(s) 2,5-7,10,11^b and 18-39 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,13,14,16 and 17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/22/02.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in Paper No. 11/06/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 3-4,8-9, and 12 are canceled without prejudice or disclaimer.
3. Claims 1-2, 5-7, 10-11, and 13-39 are pending, claims 2,5-7,10-11, and 18-39 are withdrawn from further consideration as being drawn to non-elected subject matter.
4. Claims 1, 13-14, and 16-17 are examined on the merits.

Information Disclosure Statement

5. The Information Disclosure Statement filed 2/22/2002 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112

6. Claims 1-2, 14, and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. With regard to claim 1 and dependent claims thereof in the recitation of the term "comprising" as it pertains to GM-2, GM-CSF, and HSP-90, it is indefinite because it is

unclear as to whether GM-2, GM-CSF, and HSP-90 are parts of a larger complex or molecule.

8. With regard to claim 17 in the recitation of the phrase "said mammal comprises a canine", it is unclear as to what mammal is being claimed. Does the applicant intend for the said mammal to be a mixture of a canine and something else? Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 13,14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo WS (US Patent 5,891,432). Hoo WS teaches a cellular vaccine or composition that comprises an allogeneic cancer cell or tumor cell line that comprises a tumor associated ganglioside (column 9, line 27; column 10, lines 20-25 (cell lines); column 20, line 17-27), GM-CSF cytokine (columns 6, lines 58-67, column 7, lines 1-8), and a HSP-90 heat shock protein (column 6 lines 35-37). The cancer cell lines taught by Hoo WS inherently comprise gangliosides on its surface, such as GM-2 (see Fredman P *et al* Biochim Biophys Acta 1990 Aug;1045(3):239-44 or Maeda Y *et al* Cancer Biochem Biophys 1998 Nov; 16(4):313-32 as further evidence of surface expression of ganglioside GM-2 on recited tumor cells). Hoo WS *et al* further teach the limitations of

using bacterial adjuvants such as BCG (column 12, lines 28-35) and that the cell lines can be irradiated (column 25, lines 47-49).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo WS in view of Hogge GS *et al* (Cancer Gene Therapy 1999;6(1):26-36). Claims are drawn to a composition for the induction of an immune response in a mammal, wherein the composition comprises an allogeneic cancer cell providing a tumor associated ganglioside GM-2, a GMCSF cytokine, and a HSP-90 heat shock protein (claim 1); wherein the composition further comprises a bacterial adjuvant (claim 13), wherein the adjuvant is BCG (claim 14); wherein the allogeneic cell line is rendered incapable of proliferation by radiation (claim 16); and wherein the mammal comprises a canine and said allogeneic cell is a canine cancer cell line (claim 17).

Hoo WS teaches a cellular vaccine or composition that comprises an allogeneic cancer cell or tumor cell line that comprises a tumor associated ganglioside (column 9, line 27; column 10, lines 20-25 (cell lines); column 20, line 17-27), GM-CSF cytokine (columns 6, lines 58-67, column 7, lines 1-8), and a HSP-90 heat shock protein (column 6 lines 35-37). The cancer cell lines taught by Hoo WS inherently comprise

gangliosides on its surface, such as GM-2 (see Fredman P *et al* *Biochim Biophys Acta* 1990 Aug;1045(3):239-44 or Maeda Y *et al* *Cancer Biochem Biophys* 1998 Nov; 16(4):313-32 as further evidence of surface expression of ganglioside GM-2 on recited tumor cells). Hoo WS *et al* further teach the limitations of using bacterial adjuvants such as BCG (column 12, lines 28-35) and that the cell lines can be irradiated (column 25, lines 47-49). However, Hoo WS fails to specifically characterize the type of mammal or that the cancer cell line be derived from a canine cancer cell.

The deficiency of Hoo WS is made up by Hogge *et al*, wherein a cancer cell composition or vaccine, that is derived from canine cancer cells, is used in a canine subject.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising a canine cancer cells wherein the said cell comprises GM-2 gangliosides, GMCSF cytokine and HSP-90 for the induction of an immune response in a canine. The Hogge *et al* reference is reasonably relevant to the skilled artisan because it taught that the use of a irradiated canine cancer cell line were useful in the induction of an immune response especially in an anti-neoplastic capacity for tumorigenic canine subjects. Therefore, one of ordinary skill in the art would have had motivation in combining the references because both Hoo WS and Hogge *et al* taught compositions that were capable of inducing immune responses against tumors in mammalian subjects, wherein the compositions comprised cancer cell vaccines. One of skill in the art would have had reasonable expectation of success in using allogeneic canine cancer cells for the induction of an immune

response in a mammal wherein the composition comprises a GM-2 ganglioside, a GMCSF cytokine, and HSP-90 because Hogge *et al* specifically stated that the use of such cells could prove to be a valuable translational research model and because the canine cancer cells displayed anti-neoplastic effects. The combination of other components such as GM-2 gangliosides and HSP-90 would only further enhance the specificity of the immunological effects.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
January 29, 2004



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